ATTACHMENT "A"

Facsimile Number: 571-273-8300

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application Number:

09/879,480

Applicants:

Jack C. Whittier, Barbi A. Riggs, Patrick D. Burns and

George Seidel

Filed:

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Title:

Integrated Herd Management System Utilizing Isolated

Populations of X-Chromosome Bearing and Y-

Chromosome Bearing Spermatozoa

TC/A.U:

1634

Examiner:

Carla J. Myers

Assignee:

Colorado State University through its agent Colorado State

University Research Foundation

Attorney Docket:

HrdMgmtCIP

Customer No.

33549

AFFIDAVIT UNDER 37 C.F.R. § 1.132

UNITED STATES OF AMERICA)
STATE OF COLORADO)ss.
COUNTY OF LARIMER)

I, John Schenk, duly sworn and under oath, declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true.

Since approximately 1981, I have been involved to varying degrees in the field of sexing spermatozoa and producing animals from such spermatozoa. This has included at least work with the Texas A&M University, Colorado State University, Ankony Shadow Isle, and ABS Global, Inc. Currently, I am employed by XY, Inc., the exclusive licensee of the above-captioned patent application. I am not an inventor listed on the above-captioned patent application. However, I am an inventor listed on several patents or patent applications in the field of sexing spermatozoa and producing animals from such spermatozoa, including at least: US Patent Application No. 60/400,486 entitled "Sperm Cell Process Systems"; US Patent Application No. 60/400,971 entitled "Low Pressure Sperm Separation System Using Heterospermic Insemination To Assess Sperm Function"; US Patent Application No. 09/001,394 entitled "Sheath Fluids and Collection Systems for Sex-Specific Cytometer Sorting of Sperm"; US Patent Application No. 09/015,454 entitled "System for Improving Yield of Sexed Embryos in Mammals"; US Patent Application No. 09/448,643 entitled "Multiple Sexed Embryo Production System for Mammals"; US Patent Application No. 09/478,299 entitled "Method of

Cryopreserving Selected Sperm Cells"; US Patent Application No. 09/582,809 entitled "Sex Specific Insemination of Mammals With Low Number of Sperm Cells"; US Patent Application No. 10/081,955 entitled "Multiple Sexed Embryo Production System for Mammals Using Low Numbers of Spermatozoa"; International Patent Application No. PCT/US03/24,460 entitled "Low Pressure Sperm Cell Separation System"; and International Patent Application No. PCT/US00/30,146 entitled "Methods for Improving Sheath Fluids and Collection Systems for Sex-Specific Cytometer Sorting of Sperm". My duties as Reproductive Physiologist for XY, Inc. require me to review various publications and efforts by others relevant to the field of sexing spermatozoa and producing animals from such spermatozoa and require that I have a certain level of technical expertise in these fields.

By virtue of the foregoing, I have knowledge and skill that is at least representative of those skilled in the art pertaining to sexing spermatozoa and producing animals from such spermatozoa.

I am aware of and have reviewed the specification of the above-captioned patent application. Pages 1-2 and 11-12 of the specification of this patent application as filed are attached to this affidavit as Exhibit "A". I also am aware of the claims of the above-captioned patent application as currently amended. These claims are attached to this affidavit as Exhibit "B". In discussing these claims, it should be understood that my comments are directed to Claim 28 only and do not apply to the other claims, about which I make no comment at this time.

Based on my review of Exhibit "A" and Exhibit "B", I am of the opinion that the specification of the above-captioned patent application as filed would enable those skilled in the art pertaining to sexing spermatozoa and producing animals from such spermatozoa to make and use the full scope of the invention as defined in Claim 28.

In particular, I note Claim 28 recites the step "c" of "estimating an economic cost of inducing early puberty in substantially all of said plurality of bovine female mammals", the step "d" of "estimating an economic gain of harvesting said substantially all of said plurality of bovine female mammals", and the step "e" of "utilizing a time interval, wherein said time interval begins at the time of inducing said early puberty in said substantially all of said plurality of bovine female mammals, and wherein said time interval ends at the time of harvesting said substantially all of said plurality of bovine female mammals, and wherein said time interval results in a net economic gain". As one skilled in the art pertaining to sexing spermatozoa and producing animals from such spermatozoa, it is my opinion that such a person skilled in the art would interpret the teachings of the specification as filed to disclose a method particularly including steps "c", "d", and "e" of Claim 28.

With respect to the step "c" of "estimating an economic cost of inducing early puberty in substantially all of said plurality of bovine female mammals", this concept is explained in

the specification at page 1, lines 18-30. The specification notes that in order for a SCH system to remain economically sustainable, the end product must be acceptable to the consumer. It further notes that carcasses of advanced maturity pose problems in palatability, and therefore may be penalized by financial discounts. The specification further states that the USDA has set the approximate chronological age that corresponds to the physiological maturity score of "B" or greater to be 30 months or greater. However, as noted in the specification, maturity scores may increase with increasing chronological age at a much faster rate than indicated by the USDA. Accordingly, the specification suggests that animals 24 months of age and greater more accurately correspond to USDA maturity scores of "B" or greater. Therefore, as stated in the specification, a target age of harvest for a SCH may be less than 24 months of age in order to minimize the risk of financial discounts and provide the consumer with a highly palatable product.

With respect to step "d" of "estimating an economic gain of harvesting said substantially all of said plurality of bovine female mammals", the specification states that economic sustainability is achieved by minimizing the financial discounts that result when the end product is not acceptable to the consumer. Lack of consumer acceptance, in turn, is a function of carcass maturity. While USDA guidelines suggest that harvesting prior to 30 months of age is acceptable to avoid a grade "B" maturity score, the specification teaches harvesting at or prior to the earlier age of 24 months in order to more effectively avoid a grade "B" maturity score. This fact of harvesting to a stricter standard than USDA guidelines evinces the affirmative nature of setting a time interval. In this manner, it is seen that the harvesting component of a time interval is affirmatively determined to result in a net economic gain.

Reviewing these passages from the specification, it is clear the specification teaches step "e" of "utilizing a time interval, wherein said time interval begins at the time of inducing said early puberty in said substantially all of said plurality of bovine female mammals, and wherein said time interval ends at the time of harvesting said substantially all of said plurality of bovine female mammals, and wherein said time interval results in a net economic gain". Referring to the specification at page 2, lines 1-4, it is stated that a production system in which a SCH is to rear a calf and be ready for harvest by 24 months of age may be accomplished by breeding the heifer at a non-traditional age of 9 months. The fact of breeding a heifer at such a non-traditional age evinces the affirmative nature of determining a time interval, particularly when considering that the 9-month breeding age is made necessary by having affirmatively selected a 24-month harvesting age. Also, as noted in the specification, the carcass must be of high quality but must not sacrifice the quality of the progeny. The foregoing considerations are goals of the herd management system, with economic ramifications as discussed above, that are promoted by breeding at the non-traditional age of 9 months, further evincing the affirmative nature of determining a time interval.

Moreover, it is my opinion that one skilled in the art pertaining to sexing spermatozoa and producing animals from such spermatozoa would understand that the methods described in the specification, particularly as relating to steps "c", "d", and "e" of Claim 28, are commensurate with the scope of claim 28, and are not limited to the specific parameters stated in the specification. Rather, these specific parameters as stated in the specification would be understood by such a person skilled in the art to be merely one specific embodiment of the full scope of the technique as described in claim 28. This is for at least the reason that the specification from page 11, line 19 to page 12, line 16 teaches a generalized herd management system incorporating the techniques referred to in this affidavit. Further, the specification specifically states "[w]hile Figure 7, provides a specific time line for beef cattle embodiment of the herd management invention, it is understood that is illustrative of the broad variety of species of mammal that can be managed in a similar fashion and the specific example and time line provided is not intended to limit the invention to that specific example of that time line". Reviewing these portions of the specification, and drawing on at least ordinary skill in the art pertaining to sexing spermatozoa and producing animals from such spermatozoa, such a person skilled in the art would understand that the methods described in the specification, particularly as relating to steps "c", "d", and "e" of Claim 28, are commensurate with the scope of claim 28.

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

DATED this 212 day of January, 2006.

UNITED STATES OF AMERICA STATE OF COLORADO

COUNTY OF LARIMER

SUBSCRIBED AND SWORN to before me in the County of Larimer, State of Colorado, United States of America, by John Schenk this 26 day of January, 2006. WITNESS my hand and official seal pursuant to the authority vested in me as a Notary Public by the State of Colorado.

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My Commission Expires: 2.